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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCOTT, AMANDA L	

ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,424	BERGER, RONALD D.	
	Examiner	Art Unit	
	Amanda Scott	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,15,26-31,37-41,46-49,57-60,65-68 and 73-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,15,26-31,37-41,46-49,57-60,65-68 and 73-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 February 2011* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of amendment filed 02/17/2011. An action on the merits is as follows.

Claim Objections

Claim 41 is objected to because of the following informalities: Claim 41 depends from itself. For examination purposes claim 41 will depend from claim 40. Appropriate correction is required.

Claim 48 is objected to because of the following informalities: Claim 48 recites the tissue of claim 47. Claim 48 should read the method of claim 47. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 15, 26-29, 37-39, 46-49, 57-59, 65-67, 73-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Lesh (US 5,971,983).

Regarding claims 1 and 9, Lesh discloses a catheter device comprising: an elongated body member having a distal portion; a deflection mechanism (stylet 5; column15, line 16-column 16, line 14) that extends within the elongated body and is

operably coupled to the distal portion so as to cause the distal portion to deflect with respect to a longitudinal axis of the elongated body member, a guide member (3,4); a guiding mechanism (sheath 6) coupled to the elongated body member and configured so as to guide the guide member; and wherein the guiding mechanism includes an exit portion from which the guide member exits when the guide member is being deployed from the guiding mechanism, where the exit portion is disposed with respect to the distal portion so the distal portion deflects from and with respect to the guide member, when the guide member is in deployed condition (view annotated Figure 5 below) and wherein the guiding mechanism comprises an artifact on the external surface of the elongated body member and extending axially along the elongated body member, where the artifact and the guide member are configured and arranged so the guide member is moveably retained by the artifact and so as to allow for deployment of the guide member (view annotated Figure 5 Below).

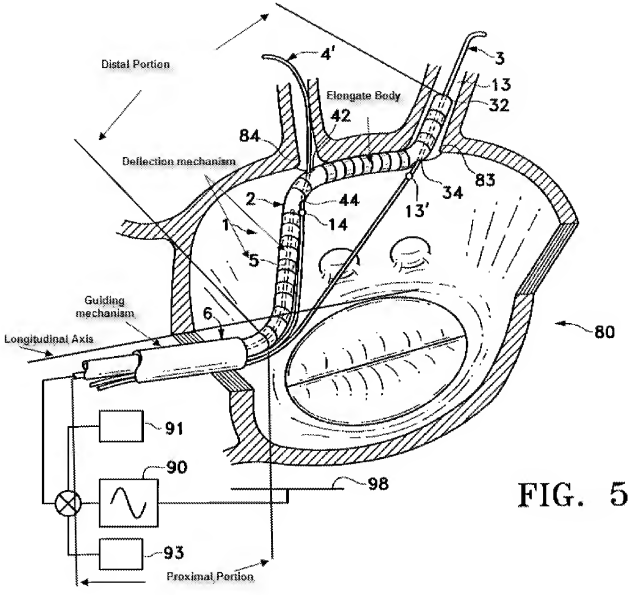

FIG. 5

Regarding claims 74 -80, Lesh discloses the catheter device of claims 1 and 15, wherein the guiding mechanism comprises a channel within the elongated body member and the exit portion comprises a through aperture in a side of the elongated body member that is in communication with the channel, where the guide member is deployed from the through aperture (view above annotate figure 5).

Regarding claim 15, Lesh discloses a catheter device comprising: an elongated body member having a distal portion; a deflection mechanism (stylet 5; column 15, line 16 – column 16, line 14) that extends within the elongated body and is operably coupled to the distal portion so as to cause the distal portion to deflect with respect to a longitudinal axis of the elongated body member; a guide member (3,4); a guiding mechanism (sheath 6) coupled to the elongated body member and configured so as to guide the guide member; an ablation device(element 20, shown in figure 6) being disposed in the distal portion, the ablation device being configured and arranged to ablate tissues proximal the ablation device; wherein the guiding mechanism includes an exit portion from which the guide member exits when the guide member is being deployed from the guiding mechanism; wherein the exit portion is disposed with respect to the distal portion so the distal portion deflects from and with respect to the guide member, when the guide member is in deployed condition; and wherein the exit portion is configured and arranged so that the distal portion when in a deflected condition is rotatable about the guide member, when the guide member is in a deployed condition (view annotated figure 5, previously presented).

Regarding claim 26, Lesh discloses a method for ablating tissue in particular atrial tissue, comprising the steps of: providing a deflection catheter device that includes a deflectable distal portion, a deflection mechanism that extends within the deflection catheter device and operably coupled to the deflectable distal portion, an ablation device disposed within the deflectable distal portion and a guide member; deploying the guide member so at least a distal portion thereof is deployed through an opening in, and

disposed in, a chamber, vessel or vein of a body; and deflecting the deflectable distal portion with respect to the guide member using the deflection mechanism (view previously presented annotated figure 5 and column 24, line55-column 25, line 20).

Regarding claim 27, Lesh discloses the tissue ablating method of claim 26, further comprising the step(s) of: contacting a tissue area including tissues to be ablated with at least a part of the deflectable portion, where the ablation device is disposed within the part; and actuating the ablation device (view previously presented figure 5).

Regarding claim 28, Lesh discloses the tissue ablating method of claim 27, further comprising the step(s) of: rotating the deflectable distal portion about the guide member; and wherein said contacting includes contacting another tissue area (the catheter is repositioned in order to contact different tissue areas to form the conduction block; column 24, line 55- column 25, line 20).

Regarding claim 29, Lesh discloses the tissue ablating method of claim 28, further comprising the steps(s) of: de-activating the ablation device during said rotating; and activating the ablation device after contacting said another tissue area(the block is formed using linear ablation lines; column 24, line 55- column 25, line 20).

Regarding claim 37, Lesh discloses a method for ablating tissue in particular atrial tissue, comprising the steps of: providing a deflection catheter device that includes a deflectable distal portion, an ablation device disposed within the deflectable distal portion, a guide member and a guiding mechanism that moveably retains at least a portion of the guide member (view previously presented annotated figure 5); localizing an end of the deflectable distal portion with respect to an opening in a chamber, vessel

or vein of a mammalian body; deploying the guide member from the guiding mechanism so at least a distal portion thereof is deployed through the opening in, and is disposed in, the chamber, vessel or vein of the mammalian body; deflecting the deflectable distal portion with respect to the guide member; contacting a tissue area including tissues to be ablated with at least a part of the deflectable portion, where the ablation device is disposed within said at least a part; and actuating the ablation device (view figure 5-8; column 24, line 55- column 25, line 20).

Regarding claim 38, Lesh discloses the tissue ablating method of claim 37, further comprising the step(s) of: rotating the deflectable distal portion about the guide member; and wherein said contacting includes contacting another tissue area (the catheter is repositioned in order to contact different tissue areas to form the conduction block; column 24, line 55- column 25, line 20).

Regarding claim 39, Lesh discloses the tissue ablating method of claim 38, further comprising the step(s) of: de-activating the ablation device during said rotating; and activating the ablation device after contacting said another tissue area(the block is formed using linear ablation lines; column 24, line 55- column 25, line 20).

Regarding claim 73, Lesh discloses the method of claim 37, further comprising the steps of: monitoring electrical conduction signals along a pulmonary vein; and identifying an origin of atrial arrhythmias as being located in the pulmonary vein based upon the monitored conduction signals (column 22, lines40-67).

Regarding claim 46, Lesh discloses a method for treating arrhythmias, comprising the step(s) of: providing a deflection catheter device that includes a

deflectable distal portion, an ablation device disposed within the deflectable distal portion and a guide member (view annotated figure 5 above); deploying the guide member so at least a distal portion thereof is deployed through an opening in, and disposed in, a vein of a mammalian body (view figure 5); deflecting the deflectable distal portion with respect to the guide member (view figure 5).

Regarding claim 47, Lesh discloses the method of claim 46, further comprising the step(s) of: contacting a tissue area including tissues to be ablated with at least a part of the deflectable portion, where the ablation device is disposed within the part; and actuating the ablation device (view figure 5).

Regarding claim 48, Lesh discloses the method of claim 47, further comprising the step(s) of: rotating the deflectable distal portion about the guide member; and wherein said contacting includes contacting another tissue area (the catheter is repositioned in order to contact different tissue areas to form the conduction block; column 24, line 55- column 25, line 20).

Regarding claim 49, Lesh discloses the method of claim 48, further comprising the step(s) of: de-activating the ablation device during said rotating; and activating the ablation device after contacting said another tissue area (the block is formed using linear ablation lines; column 24, line 55- column 25, line 20).

Regarding claim 57, Lesh discloses a method for treating arrhythmias, comprising the step(s) of: providing a deflection catheter device that includes a deflectable distal portion, an ablation device disposed within the deflectable distal portion, a guide member and a guiding mechanism that moveably retains at least a

portion of the guide member (view figure 5 annotated previously); localizing an end of the deflectable distal portion within the left atrium of a mammalian body and with respect to an opening in a vein; deploying the guide member from the guiding mechanism so at least a distal portion thereof is deployed through the opening in, and is disposed in, the vein; deflecting the deflectable distal portion with respect to the guide member; contacting a tissue area including tissues to be ablated with at least a part of the deflectable portion, where the ablation device is disposed within the part; and actuating the ablation device (view figures 5-8 and column 24, line 55- column 25, line 20).

Regarding claim 58, Lesh discloses the method of claim 57, further comprising the step(s) of: rotating the deflectable distal portion about the guide member; and wherein said contacting includes contacting another tissue area (the catheter is repositioned in order to contact different tissue areas to form the conduction block; column 24, line 55- column 25, line 20).

Regarding claim 59, Lesh discloses the method of claim 58, further comprising the step(s) of: de-activating the ablation device during said rotating; and activating the ablation device after contacting said another tissue area (the block is formed using linear ablation lines; column 24, line 55- column 25, line 20).

Regarding claim 65, Lesh discloses a method for treating left atrial arrhythmia in a left atrium of a mammalian body; comprising the steps of:
providing a deflection catheter device that includes a deflectable distal portion, an ablation device disposed within the deflectable distal portion, a guide member and a

guiding mechanism that moveably retains at least a portion of the guide member; introducing a portion of the catheter device including the deflectable distal portion into the left atrium (view annotated figure 5 previously presented); positioning an end of the deflectable distal portion with respect to an a pulmonary vein extending from the left atrium; deploying the guide member from the guiding mechanism so at least a distal portion thereof is deployed through the opening in, and is disposed in, the pulmonary vein; deflecting the deflectable distal portion with respect to the guide member; contacting a tissue area including tissues to be ablated with at least a part of the deflectable portion, where the ablation device is disposed within the part; and actuating the ablation device (view figures 5-8 and column 24, line55- column 25, line 20).

Regarding claim 66, Lesh discloses the method of claim 65, further comprising the step(s) of: rotating the deflectable distal portion about the guide member; and wherein said contacting includes contacting another tissue area (the catheter is repositioned in order to contact different tissue areas to form the conduction block; column 24, line 55- column 25, line 20).

Regarding claim 67, Lesh discloses the method of claim 66, further comprising the step(s) of: de-activating the ablation device during said rotating; and activating the ablation device after contacting said another tissue area (the block is formed using linear ablation lines; column 24, line 55- column 25, line 20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 30-31, 40-41, 60 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh (US 5,971,983) in view of Hall (US 6,652,517).

Regarding claims 30, 31, 40, 41, 60 and 68, Lesh discloses the tissue ablating method, but fails to disclose further comprising the step(s) of: rotating the deflectable distal portion about the guide member; and maintaining the ablation device in an activated condition as the deflectable distal portion is being rotated about the guide member and re-configuring the deflectable distal portion during said rotating so as to maintain the at least a part of the distal portion in contact with the tissues. However, Hall discloses a cardiac ablation apparatus for producing circumferential ablation using an elongate ablation catheter inserted into the pulmonary vein and rotating the ablation

element to achieve a continuous circumferential ablation around the pulmonary vein (view figure 11 and column 10, lines 22-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the apparatus of Lesh continuously ablate the target tissue area while rotating as taught by Hall. Doing so would achieve a continuous circumferential ablation around the pulmonary vein that isolates the atrial wall surface from the pulmonary vein taught by Hall.

Response to Arguments

Applicant's arguments, see pages 4-8, filed 02/17/2011, with respect to the rejection(s) of claim(s) 1, 15, 26, 37, 46, 57 and 65 under 35 USC 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of using a new interpretation of the Lesh reference and additional reference of Hall.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Scott whose telephone number is (571)270-7103. The examiner can normally be reached on Monday thru Thursday, 8:00 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739